Wednesday, December 19, 2018

On December 10-11, 2018, FDA hosted a public workshop, *Medical Device Servicing and Remanufacturing Activities*, as part of its effort to develop a draft guidance that will distinguish servicing activities from remanufacturing. FDA expressed intent to develop a draft guidance on this topic as part of its *May 15, 2018 report to Congress* on the quality, safety, and effectiveness of medical device servicing. Prior to the workshop, FDA drafted a white paper, *Evaluating Whether Activities are Servicing or Remanufacturing* (the “White Paper”) setting forth guiding principles relevant to servicing and remanufacturing, a flowchart to help industry stakeholders differentiate servicing from remanufacturing, applications to software, considerations for device labeling, and examples to explore the boundary between servicing and remanufacturing. The White Paper served as the primary basis for discussion during the first day of the workshop as FDA asked attendees to consider
specific questions and examples from the White Paper. The second day of the workshop focused solely on potential methods of collaboration among stakeholders to improve medical device servicing.

Below are some observations about areas of agreement among stakeholders and FDA’s perspective on servicing versus remanufacturing:

1. **Device industry stakeholders generally agree that risk-based assessments are necessary for determining whether an activity is servicing or remanufacturing.** This was an unexpected development from the workshop. One of FDA’s guiding principles in the White Paper is “employ a risk-based approach,” and we predicted OEMs would heartily agree and independent service organizations (ISOs) would vehemently disagree that risk-based processes should be a requirement. However, during the workshop session in which breakout group discussed individual examples from the White Paper, a general consensus formed that risk-based assessments are a critical in differentiating servicing from remanufacturing. Given the apparent acceptance by most of the attendees, which will likely be reflected in the written comments to the docket, as well, FDA will probably include risk-based assessments as a central element of the draft guidance.

2. **ISOs seemed to acknowledge that establishing a quality system is essential to performing medical device servicing.** This was also surprising because during FDA’s previous public workshop, "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers," held in October 2016, ISOs strongly opposed requiring servicers to implement quality systems through FDA regulation. At the recent workshop, ISOs said that any required quality system should be tailored to servicing activities, which is precisely the position OEMs advocated in 2016. OEMs were not arguing that FDA should make the quality system regulation (QSR) applicable to third-party servicers to drive reputable ISOs, which voluntarily establish quality management systems, out of business; it was to weed out the bad actors that service medical devices with no regard to maintaining device safety and efficacy. Those bad actors are not regular attendees of FDA’s workshops nor are they generally inclined to submit written comments, but they rely on large, reputable ISOs to make the argument that regulating ISOs would be inconvenient and burdensome. FDA’s refusal to regulate third-party servicing entities in the same way as OEMs remains troubling because such regulation would force ISOs without basic quality assurance safeguards to comply or get out of the business, while the ISOs with established quality systems could easily absorb the operation-specific regulations because many of them already voluntarily comply with international quality system standards.

3. **Availability of device specifications and documentation is still the most contentious issue.** As expected, OEMs and ISOs have opposite views on the types and amount of device documentation that should be available to third party servicers. OEMs are primarily concerned with protecting their intellectual
property, including device know-how and trade secrets, disclosure of which would mean forfeiture of proprietary knowledge and technology and key business advantages. ISOs argue that they need the technical specifications of devices to determine whether an activity would significantly change the safety or performance specifications of a device, and thus constitute remanufacturing. FDA appears split on this issue because it respects the IP interests of the OEMs while acknowledging that it would be difficult for ISOs to accurately differentiate between servicing and remanufacturing without some information on device specifications. At the workshop, some OEMs conceded that it may be helpful to provide certain functional specifications, such as component dimensions, ranges of movement, or other things a user can see or measure, but it is unclear how FDA will incorporate device documentation and technical specifications into the draft guidance.

4. **FDA's flowchart to help differentiate servicing from remanufacturing needs much more detailed decision points.** One of the main sessions of the workshop’s first day involved in-depth discussion and application of FDA’s proposed flowchart. During the session, breakout groups attempted to use the flowchart to determine whether the examples presented in FDA’s White Paper represented servicing or remanufacturing. Many breakout groups had long discussions about how to apply the flowchart, which was partly due to the vagueness of the examples and partly to the basic nature of the flowchart. FDA’s flowchart only has three categories of device changes—changes to components/parts/materials that contact body tissues or fluids, changes to dimensional or performance specifications of a component/part/material, and changes that introduce new or increased risk or modify performance or safety specifications—and in each case asks if the change significantly affects device performance or safety. As proposed, the flowchart leaves too much room for interpretation. A policy solution that asks servicers—many of whom are untrained or otherwise inexperienced—to make a decision about the effect of their activity is no different from the status quo in which servicers often make incorrect assessments. Instead, the 510(k) modifications guidance framework is a more appropriate model for the flowchart for because the servicing/remanufacturing question is ultimately about ensuring the continued safety, performance, and effectiveness of serviced devices similar to the evaluation comparing a new or modified device to a predicate.

5. **The draft guidance will not improve patient safety unless FDA is willing to enforce compliance.** In its May 2018 report to Congress, FDA characterized many of the device safety issues raised by manufacturers in comments to Docket FDA-2016-N-0436 and during the October 2016 public workshop as instances of remanufacturing by third parties, rather than servicing or repair. The report went on to say that remanufacturers are regulated as manufactures and must comply with applicable sections of the QSR. However, FDA has not yet addressed what resources, if any, it will devote to inspections or enforcement actions to ensure that third-party medical device servicers are only performing servicing and repair and not remanufacturing. Enforcement is a critical issue FDA must address in the process of clarifying the boundary between servicing and remanufacturing.
FDA's preparation for and comments at the workshop demonstrate that the agency genuinely wants to clarify the difference between remanufacturing and servicing to help OEMs and third-party servicers understand the boundary between regulated and unregulated activities, but the agency is attempting to avoid further regulation. While FDA may develop a guidance that is acceptable to a wide range of stakeholders on risk-based assessments, device specifications, and required documentation, it is difficult to see how FDA will ensure that third-party servicers are in compliance without requiring them to register with the agency and be subject to inspection.

FDA opened Docket FDA-2018-N-3741 to accept comments on the White Paper, and we encourage all device industry stakeholders to review the White Paper and submit comments to tell FDA how to define remanufacturing and servicing and offer instructive examples involving specific devices.

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